

(c) REMARKS

This application has been reviewed in light of the Office Action dated June 8, 2010. Claims 1, 2, 4, 11, 14, 25 and 26 are presented for examination, with claim 1 being in independent form. Claim 1 has been amended to better define the intended invention and claim 14 has been amended to correct a typographical error. Support for the amendment to claim 1 may be found, for example, on page 2, lines 34 through 37, of the subject specification as filed. No new matter has been added. Favorable reconsideration is requested.

Claim 14 has been objected to for an informality. In response, claim 14 has been carefully reviewed and amended in accordance with the suggestion made by the Examiner on page 2 of the Office Action. Specifically, it has been amended to add the word “wherein” after “Claim 2.” Accordingly, Applicants believe that the objection has been obviated and respectfully request withdrawal thereof.

Claims 1, 2, 4, 11, 14, 25 and 26 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,994,329 (Daifotis) in view of either U.S. Patent No. 4,817,819 (Kelly) or U.S. Patent No. 5,265,728 (Allendorf) and further in view of Palo Alto Medical Foundation, “Calcium and Nutrition PAMF Patient Health Information,” January 2002 (Palo Alto Medical Foundation). Applicants respectfully traverse the rejections.

Prior to addressing the grounds of rejection, Applicants wish to briefly review certain features and advantages of the present invention. The invention is related to a kit for promoting the proper sequential and continuous oral administration of a bisphosphonate and an accompanying nutrient over a 28 day period of time. The kit contains 4 unit doses of the bisphosphonate, wherein each dose is to be given once a week;

24 unit doses of a nutrient selected from the group consisting of calcium, vitamin D, calcium and vitamin D, and a combined unit dose of calcium and vitamin D, and unit doses of calcium are about 400 mg to about 1500 mg of elemental calcium per day and unit doses of vitamin D are about 100 IU to 10,000 IU per day; and a blister card containing the unit doses, which are arranged in order of their use across the blister card. Further, the kit combines administration of an active with a nutrient while it provides a means wherein simultaneous dosing of the bisphosphonate and the nutrient is avoided. This combined administration increases the benefits achieved by the treatment since osteoporosis treatments are less effective in individuals with calcium and vitamin D deficiency. Whereas physicians generally need to evaluate patients' calcium and vitamin D sufficiency and provide supplements as needed, along with guidance, the present invention eliminates these additional unwanted steps.

The subject kit also increases patient compliance and ease of administration. Whereas with conventional kits, patients may forget or simply not follow instructions regarding when to take the active versus when to take the nutrient, with the subject invention, administration is simplified and clarified. Still further, since bisphosphonate and calcium should not be taken at the same time because the calcium interferes with the absorption of the active (page 2, lines 28-38), the kit clearly teaches patients to take the accompanying nutrient on days only when not taking the active, thereby avoiding any problems associated with simultaneous dosing. *Id.* This is a novel advancement over the prior art.

Daifotis is directed toward a method for inhibiting bone resorption employing a bisphosphonate according to a continuous schedule. As acknowledged by the Examiner, Daifotis fails to teach or suggest a blister pack as disclosed in the present

invention. In addition, while Daifotis discloses the use of a bisphosphonate according to varying dosing schedules, it fails to specifically recite or suggest, by way of example, any regimens administering doses of a nutrient. At column 13, lines 61-65, Daifotis discloses a list of possible additional dosages to the kit, including calcium, as a potential memory aid, however, it fails to specifically identify vitamins, or, more specifically, vitamin D. Further, Daifotis fails to offer any guidance as to the amount of calcium or other nutrient that might be administered in unit doses in the kit and fails to appreciate the benefits achieved by taking a nutrient while eliminating the problems of simultaneous dosing of a nutrient and bisphosphonate, as recited in the present invention and explained above. Therefore, for all of the reasons set forth above, Applicants submit that Daifotis fails to render the presently claimed invention obvious.

Kelly and Allendorf fail to remedy the deficiencies of Daifotis. Both Kelly and Allendorf are cited by the Examiner for teaching blister packs for storing and dispensing tablets. However, neither of the references teach administration of unit doses of an accompanying calcium, vitamin D, or a nutrient of any kind. They merely teach that seven tablets in the blister pack might be a placebo or non-active tablet. Further, there is clearly no disclosure or suggestion of the amount of calcium, or vitamin D to be administered in the unit doses as presently claimed, e.g., about 400 mg to about 1500 mg of elemental calcium per day and about 100 IU to 10,000 IU per day. Still further, neither Kelly nor Allendorf teach or suggest avoidance of simultaneous daily dosing of the bisphosphonate and the nutrient, or the benefits achieved thereby, namely increased effectiveness of the active. Therefore, Applicants respectfully submit that Daifotis, Kelly and Allendorf, in any permissible combination, fail to render the present invention obvious.

Palo Alto Medical Foundation fails to remedy the deficiencies of Daifotis, Kelly and Allendorf. This reference is cited by the Examiner for disclosing the recommended doses of calcium and vitamin D. However, the Examiner acknowledges that Palo Alto Medical Foundation fails to disclose a kit. It only teaches information on these supplements for patient health, including recommended daily doses. Therefore, Palo Alto Medical Foundation fails to specify a kit containing an active ingredient, and fails to offer any guidance on the dosing of the active in relation to the supplement and the benefits that may be achieved by a kit whereby simultaneous dosing is avoided. Accordingly, Applicants respectfully submit that Daifotis, Kelly, Allendorf and Palo Alto Medical Foundation, in any permissible combination, fail to render the present invention obvious and respectfully request withdrawal of the § 103 rejections.

In view of the foregoing amendments and remarks, favorable reconsideration and passage to issue is earnestly requested. Should the Examiner believe that issues remain outstanding, the Examiner is respectfully requested to contact Applicants' undersigned attorney in an effort to resolve such issues and advance the case to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

/Raymond R. Mandra/
Raymond R. Mandra
Attorney for Applicants
Registration No. 34,382

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200

FCIS_WS 5492093_1.DOC